

## NIH OFFICE OF RESEARCH ON WOMEN'S HEALTH SEMINAR SERIES



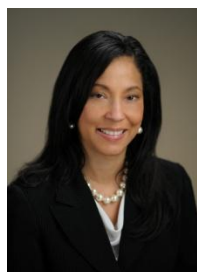
# CLINICAL RESEARCH, INCLUSION AND YOU – A Scientific Forum

MAY 16, 2013  
NATCHER CONFERENCE CENTER  
BUILDING 45, BALCONY B  
NIH CAMPUS, BETHESDA, MD

“Clinical Research, Inclusion, and You—A Scientific Forum,” was the signature event for National Women’s Health Week at NIH activities and the annual ORWH scientific seminar. The scientific forum explored the relevance and necessity of including women and minorities in clinical research, planning and reporting on sex/gender analysis, and health disparities among women of color.

Guest speakers were Dr. Mary Foulkes from George Washington University and Dr. Sharon Davis from the National Institute on Minority Health and Health Disparities, NIH. Ms. Christine Eads discussed a patient’s perspective from her own experience as a clinical trial participant

A panel discussion followed the presentations with questions from the audience, including viewers accessing the seminar on the Web.



### **Welcome and Introductions**

*Janine A. Clayton, M.D., Director, ORWH*

Dr. Janine Clayton noted that the forum was presented as part of annual National Women’s Health Week at NIH activities-- nationwide initiative coordinated by the DHHS Office on Women’s Health, encouraging federal agencies, families, communities, businesses, health organizations, and other groups to work together to promote women’s health and its importance to family and community health. The mission of the ORWH is to improve women's health through supporting biomedical and behavioral research including study of the role of sex and gender in health and disease at NIH. Dr. Clayton applauded the efforts of the former leaders of the ORWH—Ruth Kirschstein,

M.D., and Director Vivian Pinn, M.D. respectively, who helped establish ORWH and refine the office's research focus.

Dr. Clayton introduced Mary A. Foulkes, Ph.D., a research professor from the George Washington University School of Public Health and Health Services. Dr. Foulkes has worked with the ORWH on issues of inclusion of women in research, sex-specific reporting of research results, and valid analyses.



### **The Research Continuum from Inclusion to Reporting**

*Mary A. Foulkes, Ph.D., George Washington University School of Public Health and Health Services*

Dr. Foulkes described the clinical research continuum, which features creating the initial hypothesis, designing the research project and developing a protocol, enrolling participants and performing the research, publishing and presenting the results, citing and discussing the work, and developing subsequent hypotheses. She noted the importance of including women and minorities in various stages of the research continuum, especially in the development of hypotheses and research design. She presented a history of the growing attention to the inclusion of women and minorities as participants in clinical research in recent decades—a progress spurred by federal legislation.

Referring to Phase III clinical studies, Dr. Foulkes stated that the development of protocols occurs in light of four possibilities regarding sex differences: (1) the past evidence strongly suggests differences between female and male subjects, (2) the past evidence strongly suggests no differences between female and male subjects, (3) there is no clear evidence for either the presence or absence of such differences, or (4) there are exclusions based on biology or health. Most NIH-supported clinical research falls within the third possibility (no clear evidence either way) and therefore should include both women and men as participants.

Dr. Foulkes noted the selection process for NIH trials and referred to a published review of a period beginning in 1994 that produced 268 publications of results from Phase III clinical trials that included men and women. The proportion of trials including both men and women rose steadily during the period. Some examples from the results of the review are as follows:

- Of the 268 published trials, 9 percent were stratified by sex.
- Only 28 percent of the published reports mentioned the issue of differences based on sex/gender.
- Of that 28 percent, a small fraction simply stated “no differences” without elaborating.
- Less than 5 percent of the published reports included a discussion of potential selection bias.

Dr. Foulkes stressed that failure to address sex and gender differences more widely and in a more robust fashion makes it difficult to develop strong protocols. Future researchers need data with which to estimate variances (as one example).

Dr. Foulkes noted that enrollment of subgroups (men/women, minorities) in a trial at different rates can lead to a misunderstanding of results when trials are halted early. Different dropout rates for subgroups also may lead to problems in translating results. Such information should be included in publications and their supplementary material.

In summary, Dr. Foulkes encouraged (1) an emphasis on inclusion of women and minorities, (2) the monitoring of enrollment, (3) the dissemination of more complete information, and (4) the creation of satisfactory, or welcoming, environments for research participants, especially women and minorities.

Dr. Clayton stressed the fact that the enrollment of women in trials does not ensure that reporting of results for women will occur. The formulation of research questions is crucial.

Dr. Clayton introduced Sharon K. Davis, Ph.D., a senior scientist in the National Institute on Minority Health and Health Disparities, of NIH's Division of Intramural Research.



### **Health Status among Women of Color**

*Sharon K. Davis, Ph.D., National Institute on Minority Health and Health Disparities*

Dr. Sharon K. Davis described the status and trends in health disparities for women of color, including African Americans, Hispanics, Latinos, Alaskan natives, American Indians, Asian Americans, and Pacific Islanders. Although secular improvements in health have occurred in recent years—mainly because of advances in technologies—the improvements for women of color have lagged, leading to wider gaps.

Dr. Davis presented data comparing the subgroups. The data indicated that African-American women have the highest rate for low birth weight babies, the highest mortality rate for all causes, the highest mortality rate for heart disease, and more. American Indian women and Alaskan native women have the highest rates for motor vehicle-related mortality. Vietnamese American women have the highest rate for cervical cancer. Low-income white women have health profiles similar to those of African-American women.

Dr. Davis discussed causal factors for the trends, including lifestyles (modifiable) and hereditary factors (non-modifiable). Social determinants include low socioeconomic status, being the single head of a household, suffering from poor access to advanced medical technologies, and exposure to psychosocial factors.

Interventions that might improve the health trends for minorities include culturally tailored interventions and health education campaigns, expanded access to health care under state Medicaid programs, and the allocation of resources for neighborhood activities. Dr. Davis

emphasized that we need innovation in neighborhood interventions, which should involve local community stakeholders.

Dr. Clayton stressed the fundamental need to attend, in a focused way, to issues involving health. For example, when developing a program targeting a health need, one should ask whether there are differences (the need, strategy, etc.) for females and males.

Dr. Clayton introduced Christine Eads, a participant in an NIH clinical trial and the founder of Duffy House, a program that aids women and children who have survived sexual assaults.



### **Clinical Research Made a Difference for Me**

*Christine Eads, Founder, Duffy House*

Christine Eads presented a patient's perspective on unique health issues for women and the need for more women to participate in clinical trials. She provided details from her own experience with premature ovarian insufficiency/failure, a condition in which a woman's ovaries do not function normally that often leads to infertility. Ms. Eads described years of frustration associated with being misdiagnosed by many physicians. A recommendation by a friend brought her to NIH for consultation.

She eventually enrolled in an NIH-sponsored clinical trial and received an accurate diagnosis and treatment for her condition. In addition to medical treatment, the clinical trial protocol offered counseling and support, which Ms. Eads stated was important to her mental health as she coped with the likely possibility of never having a biological child. She mentioned the close relationships she developed with the treatment team. During the clinical trial and supportive counseling, Ms. Eads learned about other paths to becoming a parent, such as adoption. She became a foster mother to a teenage girl and in this way started the family she had always wanted.

Ms. Eads expressed great appreciation for the benefits of the clinical trial and stressed the importance of the research on premature ovarian insufficiency and for so many other conditions affecting women. Nine months into the trial, she became pregnant, and she had a son.

### **Questions and Panel Discussion**

In a final session, the three presenters took questions from the audience, including those viewing on the Web.

In response to a question about potential changes in inclusion policies, Dr. Foulkes stated that each investigator must consider the research question in the abstract and develop a plan that addresses disease and patients appropriately. The investigator should consider whether collaborations with other institutions are warranted. Dr. Davis called for educating the community that is targeted by the research and for partnering with stakeholders (NAACP, synagogues, etc.).

Ms. Eads was asked to elaborate on her experience with illness and clinical trials. She again stressed the importance of the counseling that was offered as part of the experience. The physician-investigators were very understanding, she said. One area that might be improved, according to Ms. Eads, is making clinical trial participants aware of health-related resources once a trial is completed.

In response to a question about the types of technologies that have helped to improve health for women and minorities, Dr. Davis cited mammograms, EKGs, and hypertension medications—especially when such technologies are supported by Medicaid.

Ms. Eads stated that women need to be informed better about available clinical trials and other options related to health care. Outreach to women through churches, beauty parlors, and other venues that women congregate might help, she suggested.

Dr. Clayton added that investigators need to be aware of issues of sex and race in specific research cases. Health care providers need to become aware of ongoing and developing clinical trials. Ms. Eads proposed that experts visit clinics and physicians' offices to speak about issues of sex and race—for example; they might also stress the fact that the menstrual cycle be used as a “vital sign” or health indicator. When a woman's menstrual cycle isn't functioning normally, it should indicate a need for follow up and further investigation of potential causes that could require treatment.

It was noted that the Web site [clinicaltrials.gov](http://clinicaltrials.gov) does not appear prominently during Google searches regarding health and health care. The site remains underutilized. Perhaps Google could be encouraged to present more links to [clinicaltrials.gov](http://clinicaltrials.gov) and to relevant twitter and Facebook areas. The presenters suggested creating a clinical trials site more welcoming to patients, rather than researchers.

In response to a question about trends showing better health results for some minorities (e.g., lower heart disease mortality for Latinas and Asian Americans), Dr. Davis noted that the data based on national sampling by the Centers for Disease Control and Prevention (CDC) lacks granularity. Various strengths and weaknesses are not revealed by the gross figures for the subgroups. Socioeconomic status would seem to be a large factor, yet that is not always the case. Context is important. Granularity is important.

In response to an online question about exclusion factors for clinical trials being potentially difficult to overcome, Ms. Eads noted that exclusion factors depend on the particular trial. Potential participants should inquire about multiple trials, seeking those that are most appropriate for their personal health concern. Web sites for trials tend to be very clear about their needs and exclusions (age groups, etc.) and Ms. Eads noted that she didn't encounter any difficulty enrolling. Dr. Foulkes noted that, in some cases, an exclusion factor can be eliminated simply by having the patient wait for an amount of time to pass (for example, to complete a regimen of antibiotics).

Ms. Eads stated that she didn't feel that applying for her trial was stressful or cumbersome, especially compared to the great stress she had experienced for years with her condition

misdiagnosed or undiagnosed. In addition to its intramural clinical trials, the NIH supports a vast number of extramural institutions that conduct trials throughout the nation. Patients should investigate the variety.

It was noted that some health disparities have featured, over time, a flipping between minority groups and majority groups. Examples include problems with substance use, certain instances of mental illness, and certain group-risks for suicide.

The panel agreed on the importance of social policies. Dr. Davis noted that, although we might agree on needed changes in lifestyles, it can be difficult to engage populations. Policies and interventions that lead to expanded access to medical care can be a great help. NIH's support of a diabetes prevention program is a good example.

### **Closing**

Dr. Clayton thanked the speakers and other meeting participants. She encouraged them to provide feedback on this and similar seminars. She noted that during National Women's Health Week at NIH, the ORWH offers various materials on women's health-related topics and information about clinical trials and clinical resources at an exhibit in the NIH Clinical Center.

Visit [Inclusion of Women and Minorities in NIH Clinical Research](#) for more information